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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NO. |
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5949

EXAMINER

DENTZ, B

12M2/0726

ART UNIT PAPER NUMBER

BASY PAT. HUMANION
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DATE MAILED: 1003

07/26/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days~~, ~~whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-17 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-17 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☒ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Shiota et al. This US Patent discloses that N-2,3-dihydrobenzofuranyl-ureas where the urea group is substituted at the 5, 6, 7, or 8-position are strong ACAT enzyme inhibitors and also have strong anti-hyperlipidemic and anti-atherosclerotic activity. Since the latter is known to be an inflammation of the arterial wall the instant utilities are the same.

Note that the urea group can be in the 5-position, i.e. P can be an urea group. Note that the 7-position may be unsubstituted or substituted by a C₁-C₂₀ alkyl group.

See col. 3 and 4 and col. 5, line 25.

Claims 1-17 are rejected under 35 U.S.C. § 103 as being unpatentable over Shiota et al.

This reference also renders obvious the instant dihydrobenzofuran-5-yl ureas as anti-inflammatories. See compound no. 306 at col. 29 and 30. See also compound no. 521, 522, and 525 at col. 53, 54.

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Claims 1, 2, 12, and 13 are rejected under 35 U.S.C. § 103 as being unpatentable over Herbst in view of Shiota et al. The former U.S. Patent teaches that ureas and thiourea substituted by a 2-methyl-2,3-dihydrobenzofuran-5-yl groups are useful as hypoglycemic, diuretic, and anti-hypertensive agents. The hypoglycemic and diuretic activities are very close to the instant anti-inflammation activities. The much broader Shiota et al. relates to similar pharmaceutical activities. It discloses 2,3-dihydro-benzofuranyl-ureas including those in which the urea group is attached to the 5-position of 2,3-unsubstituted benzofuranyl moieties. This renders obvious the instant 2,3-unsubstituted-2,3-dihydrobenzofuran-5-yl ureas.

Claims 1 and 2 are rejected under 35 U.S.C. § 102(b) as being anticipated by Lettieri et al. The reference discloses N-chroman-6-yl-N¹-optionally-substituted aryl or alkyl ureas meeting the above instant claims.

Claims 1-17 are rejected under 35 U.S.C. § 103 as being unpatentable over Shiota et al. in view of Herbst et al. and Lettieri et al. This rejection is like the previous rejection made earlier over the first 2 references. Further Lettieri et al. discloses that the chroman-6-yl ureas have pharmaceutical properties analogous to the corresponding 2-methyl-2,3-dihydrobenzofuranyl ureas of Herbst et al. which ties in within the generic teaching of the pharmaceutical activity of 2,3-

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dihydrobenzofuran-5,6,7- or 8-yl ureas of Shiota et al. Thus the instant chromans and oxepins are considered obvious, as are their pharmaceutical claims.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Adler et al. The generic disclosure as well as specific Ex. 2 at col. 13 and 14 meets claim 1 when a ring is formed which includes the urea nitrogens.

Claims 1 and 2 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cooke et al. This U.S. Patent discloses 1-dihydrobenzofuran-5-yl-(1-alkyl or 1-alkyl or 1-cycloalkylalkyl-ureas) as intermediates for furoquinazolinones which are useful as pharmaceuticals. See compound IIICF at col. 4. For specifically disclosed compounds see col. 10, lines 4 and 5 and col. 13, lines 33-35.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Duggan.

This U.S. Patent discloses insecticidal compounds in which one of the urea N's is part of a pyrazoline ring. The other N of the urea may be attached to 2,3-dihydrobenzo-furan-5-yl or chromanyl groups. See Ex. 81-83 e.g.

Claims 1-3 and 12-17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Takeuchi et al.

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It discloses N-(2-dihydrocarbylamino-(including pyrrolidin-1-yl) 1-optionally substituted phenylethyl)-N¹-condensed heterocyclyl ureas as analgesics. The N¹-substituent is 2,3-dihydrobenzofur-5-yl in one of the Examples. See the print-out from a computer search showing said compound.

Claims 1 and 2 are rejected under 35 USC 102(b) as being anticipated by Neumann. This U.S. Patent discloses N-[2,3-dihydrobenzofuran-5-yl)thiourea as an intermediate for 5-(imidazolin-2-ylamino)2,3-dihydrobenzofuran. See Example Number (a) at col. 6, which is made in an analogous manner to Example 5.

Claims 1-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims do not particularly point out the invention because applicants give definitions in the specification of various chemical terms used in said claims which are contrary to accepted chemical usage. For example, alkyl is said to include a hydrocarbon chain which may be cyclic or unsaturated or substituted. The normal meaning of alkyl is a saturated acyclic hydrocarbon group.

If substituted alkyl is intended it should be specified.

If cycloalkylalkyl is specifically intended it should be specified.

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At the end of line 3 of claim 4 ",", should be "or". Then in claim 5 "or straight alkyl with a terminal cycloalkyl" finds no antecedent basis in claim 1 as does unsaturated with one double bond between non-terminal C atoms. For Z in the claims the definitions at page 5, lines 6-14 are suggested.

In Independent claim 8, R₃ can be phenethyl or benzyl. These values do not occur in claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as for failing to provide an adequate description of the invention for the above reasons.

Claims 1-17 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dentz whose telephone number is (703) 308-4544. The fax phone number for this Group is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

DENTZ:jd
JULY 17, 1996



**BERNARD DENTZ
PRIMARY EXAMINER
GROUP 1200**